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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,909	09/14/2006	Junkuan Wang	112701-753	1906
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 04/07/2009		EXAMINER MI, QIUWEN	
			ART UNIT 1655	PAPER NUMBER
			NOTIFICATION DATE 04/07/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/598,909

Applicant(s)

WANG ET AL.

Examiner

QIUWEN MI

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-14, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment in the reply filed on 1/27/09 is acknowledged. Claims 1-21 are pending. Claims 9-11, 15-19 are withdrawn as they are directed toward non-elected invention groups. **Claims 1-8, 12-14, 20, and 21 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 12-14, 20, and 21 are newly rejected under 35 USC § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pruthi et al (US 6,264,982), as evidenced by Sivakumar et al (Polyphenolic constituents of the flowers of

Berberis aristata, Journal of the Indian chemical society, 68 (9): 531-2, 1991)*, Bubicz (Occurrence of carotenoids in fruits of the genus *Berberis*, Bulletin De L'Academie Polonaise Des Sciences, 13 (5): 251-5, 1965)*.

This is a new rejection necessitated by the Applicant's amendment filed on 1/27/09.

Pruthi et al teach a composition for a dietary supplement (thus an oral composition, an oral pharmaceutical composition) for use in treating hemorrhoids includes 30-80% Indian barberry extract by weight (see Abstract). Pruthi et al indicate Indian Barberry is known botanically as *Berberis aristata* (col 2, line 1-5), and Indian barberry plant parts (thus a plant material, a berry) are broken into small pieces and then mixed with equal amounts of either water or milk (thus from animal origin) (thus the carrier milk will extract the lipophilic and hydrophilic bioactive components from Indian barberry) of in a first mixing bowl or chamber to produce a first mixture. The first mixture is heated to a boil and is maintained at a boil for 2 to 3 minutes. It is critical that this boiling time is not exceeded, as this will destroy the healing properties of the herbal ingredients. After heating, the first mixture is allowed to cool to room temperature and is then filtered to remove leaves, dirt, and other particulate (thus excluding insoluble fibers) to yield an extract (thus a liquid) (col 3, lines 20-30).

As evidenced by Sivakumar et al, *Berberis aristata* contains polyphenolic constituents such as quercetin (thus a flavonoid, a flavanol, a hydrophilic bioactive component), etc (page 531, 1st column, 2nd paragraph).

As evidenced by Bubicz, in the fruits of the 34 species of the genus *Berberis* (including *Berberis chitria* (page 254), the same as *Berberis aristata*), the fruits of all the species contain

the same carotenoids: phytofluene, beta-carotene (thus a lipophilic bioactive component), lutein, zeaxanthin and flavoxanthin (page 254, last paragraph).

Since Pruthi et al teach extract the claimed plant material with the claimed carrier milk, it is deemed that bioavailability, miscibility and stability are improved.

Pruthi et al do not explicitly teach milling the material in the milk or milk protein-containing carrier. However, it is noted that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed method would have been obvious to those of ordinary skill in the art with the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the art rejection above, please note that Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' method

differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Applicant argues that the cited reference does not teach the bioavailability, miscibility and stability are improved.

This is not found persuasive. Since Pruthi et al teach extract the claimed plant material with the claimed carrier milk, it is deemed that bioavailability, miscibility and stability are improved.

Applicant also argues that the cited reference does not teach milling the material in the milk.

It is true that Pruthi et al do not explicitly teach milling the material in the milk or milk protein-containing carrier. However, it is noted that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In addition, by the process of mixing small pieces of Indian barberry plant parts with equal amounts of milk as taught by Pruthi et al will inherently extracting the lipophilic and hydrophilic bioactive components from Indian barberry, no matter whether the plant materials in milled in the milk or not. The milling process might increase the extraction efficacy, but this is not a method claim, and there is no requirement regarding the amount of lipophilic and hydrophilic bioactive components in the claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655